**STAGE 1 - RESEARCH ETHICS APPROVAL FORM**

Research by students and staff at the University must receive ethical approval before any data collection commences. Applications may be made on the Research Ethics Online system or via approval forms.

If using the approval forms, applicants complete this Stage 1 - Research Ethics Approval Form which includes the Risk Checklist.

For student projects classified as Risk Category 1 (e.g., many literature reviews), these can be approved on this Stage 1 – Research Ethics Approval Form by the Research Supervisor.

Applicants whose research studies are classified as Risk Category 2 or 3 must also complete and submit the separate Stage 2 - Research Ethics Approval Form.

Guidance for completion of this form and the application process is provided on pages 3 and 4.

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| **APPLICANT DETAILS** | | |
| Your name (if a group project, include all names) | Soya Shrestha | |
| School | The British College | |
| **STATUS** | | |
| * Undergraduate student | **Checkmark** | |
| * Taught Postgraduate student | ☐ | |
| * Research Postgraduate student | ☐ | |
| * Staff member | ☐ | |
| * Other (give details) |  | |
| **IF THIS IS A STUDENT PROJECT** | | |
| * Student ID | 77356846 | |
| * Course title (eg, BA (Hons) History) | BSc. Hons Computing | |
| * Student email | ssoya22@tbc.edu.np | |
| * Research Supervisor’s name   Or Director of Studies’ name | Rohit Raj Pandey | |
| **THE PROJECT/STUDY** | | |
| Project /study title | Smart Vitals: A portable Health Monitoring System | |
| Start date of project | 17th December, 2024 | |
| Expected completion date of project | 12th May, 2025 | |
| Project summary – please give a brief summary of your study (maximum 100 words) | | |
| Smart Vitals is a portable health monitoring device designed to measure essential vital signs such as heart rate, SpO₂ (oxygen saturation), ECG, blood pressure, and body temperature in real-time.  The system uses the ESP32 microcontroller, with sensors like the MAX30100 (SpO₂ & heart rate), AD8232 (ECG sensor), and a temperature sensor. Collected data is displayed on the OLED screen for quick local access and transmitted via Wi-Fi to the mobile app, which offers a graphical representation of vitals. The app also enables the users to receive real-time alerts when abnormal readings are detected, ensuring timely medical interventions. | | |
| **CONFIRMATION STATEMENTS** | |  |
| **The results of research should benefit society directly or by generally improving knowledge and understanding. Please tick this box to confirm that your research study has a potential benefit.** *If you cannot identify a benefit you must discuss your project with your Research Supervisor to help identify one or adapt your proposal so the study will have an identifiable benefit.* | | **Checkmark** |
| **Please tick this box to confirm you have read the Research Ethics Policy and the relevant sections of the Research Ethics Procedures and will adhere to these in the conduct of this project.** | | **Checkmark** |

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| **RISK CHECKLIST - Please answer ALL the questions in each of the sections below – tick YES or NO**  **WILL YOUR RESEARCH STUDY……..?** | | **YES** | **NO** |
|  | Involve direct and/or indirect contact with human participants? | **Checkmark** | **☐** |
|  | Involve analysis of pre-existing data which contains personal or sensitive information not in the public domain? | **☐** | **Checkmark** |
|  | Require permission or consent to conduct? | **Checkmark** | **☐** |
|  | Require permission or consent to publish? | **Checkmark** | **☐** |
|  | Have a risk of compromising confidentiality? | **Checkmark** | **☐** |
|  | Have a risk of compromising anonymity? | **Checkmark** | **☐** |
|  | Collect / contain sensitive personal data? | **Checkmark** | **☐** |
|  | Contain elements which you OR your supervisor are NOT trained to conduct? | **☐** | **Checkmark** |
|  | Use any information OTHER than that which is freely available in the public domain? | **☐** | **Checkmark** |
|  | Involve respondents to the internet or other visual/vocal methods where participants may be identified? | **☐** | **Checkmark** |
|  | Include a financial incentive to participate in the research? | **☐** | **Checkmark** |
|  | Involve your own students, colleagues or employees? | **☐** | **Checkmark** |
|  | Take place outside of the country where you are enrolled as a student, or for staff, outside of the UK? | **☐** | **Checkmark** |
|  | Involve participants who are particularly vulnerable or at risk? | **☐** | **Checkmark** |
|  | Involve any participants who are unable to give informed consent? | **☐** | **Checkmark** |
|  | Involve data collection taking place BEFORE informed consent is given? | **☐** | **Checkmark** |
|  | Involve any deliberate deception or covert data collection? | **☐** | **Checkmark** |
|  | Involve a risk to the researcher or participants beyond that experienced in everyday life? | **☐** | **Checkmark** |
|  | Cause (or could cause) physical or psychological harm or negative consequences? | **☐** | **Checkmark** |
|  | Use intrusive or invasive procedures? | **☐** | **Checkmark** |
|  | Involve a clinical trial? | **☐** | **Checkmark** |
|  | Involve the possibility of incidental findings related to health status? | **Checkmark** | **☐** |
|  | Fit into any of the following security-sensitive categories: concerns terrorist or extreme groups; commissioned by the military; commissioned under an EU security call; involves the acquisition of security clearances? If yes, see the guidance. | **☐** | **Checkmark** |

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| **CLASSIFICATION**  **The following guidance will help classify the risk level of your study** | **Tick the box which applies to your project** |
| If you answered **NO** to all the above questions, your study is provisionally classified as **Risk Category 1** (literature reviews will be Risk Category 1). | **☐** |
| If you answered **YES** to any question from 1-13 and **NO** to all questions 14-22, your study is provisionally classified as **Risk Category 2**. | **Checkmark** |
| If you answered **YES** to any question from 14-22, your study is provisionally classified as **Risk Category 3**. | **☐** |
| If question 23 has been answered **YES**, your application will be reviewed by the Chair of the University Research Ethics Sub-committee | **☐** |

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| **DECLARATION AND SIGNATURE/S** | | | |
| *I confirm that I will undertake this project as detailed above. I understand that I must abide by the terms of the approval and that I may not make any substantial amendments to the project without further approval.* | | | |
| *Signed* |  | *Date* | 28th February |

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| **FOR RISK CATEGORY 1 STUDENT PROJECTS** | | | | | |
| **Approval from the Research Supervisor or Director of Studies for a student project:**  *I have discussed the ethical issues arising from the project with the student. I approve this project.* | | | | | |
| *Name* | Rohit Raj Pandey | *Signed* |  | *Date* | 2nd March |

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| **NEXT STEP** |
| **RISK CATEGORY 1 PROJECTS**: IF YOUR PROJECT HAS BEEN CLASSIFIED AS RISK CATEGORY 1:   * Students: The Research Supervisor should return the signed form to the student and send a copy to the Local Research Ethics Co-ordinator and where relevant, the Research Module Leader, for information. * Staff: Submit this form to your Local Research Ethics Co-ordinator.   **RISK CATEGORY 2 OR 3 PROJECTS:** IF YOUR PROJECT HAS BEEN CLASSIFIED AS RISK CATEGORY 2 OR 3 please complete the Stage 2 - Research Ethics Approval form and submit both forms together with supporting documentation.  **QUESTION 23:** If this question has been answered **YES**, your application will be reviewed by the Chair of the University Research Ethics Sub-committee, and the forms should be submitted directly to Professor Karl Spracklen, [k.spracklen@leedsbeckett.ac.uk](mailto:k.spracklen@leedsbeckett.ac.uk). You will need to submit the Security-sensitive research form available from the Research Ethics web page.  *Research ethics application forms will be retained in the School for the purposes*  *of quality assurance of compliance and audit for THREE years* |

**NOTES FOR COMPLETION**

*University Research Ethics Policy and Procedures:* The University Research Ethics Policy and Research Ethics Procedures should be read prior to commencing this application. Consideration of the application by the reviewer/s will be undertaken in accordance with the Policy and Procedures.

*External requirements for the project:* Applicants should consider if there are requirements by any relevant professional, statutory or regulatory body, or learned society, which may be relevant to the project or if the project also requires external approval.

**Submission**

* Student applicants: email the typed form/s to your Research Supervisor or Director of Studies.
* Staff applicants: email the typed form/s to your Local Research Ethics Co-ordinator.

**How to complete the form**

You can navigate through the form by using the tab keys. If you prefer to complete a normal Word document, you can unlock the form by selecting the ‘Restrict Editing’ button on the Developer tab, then click on ‘Stop Protection’. The boxes should expand to allow space for your text.

**Signatures**

Electronic/typed signatures are acceptable for emailed forms, as the emails provide the audit trail for all parties’ agreement and approval of the forms (e.g., student applicant →Research Supervisor →Local Research Ethics Co-ordinator).

**Outcome**

Applicants will be advised of the outcome of the application by receipt of the signed form fromm:

* The Research Supervisor or Director of Studies for Risk Category 1 student projects;
* The Local Research Ethics Co-ordinator or the School level group for Risk Category 2 and 3 projects.

YOU MAY ONLY BEGIN ANY DATA COLLECTION ONCE YOU RECEIVE NOTIFICATION THAT THE PROJECT HAS ETHICAL APPROVAL. If the circumstances of your research study change after approval it is your responsibility to revisit the Risk Checklist and complete a further application.

**Advice**

When completing the Stage 1 - Research Ethics Approval Form,. if you are uncertain about the answer to any question, read the relevant section of the Research Ethics Procedures document, and if you are still unsure:

* if you are student, seek guidance from your Research Supervisor or Director of Studies;
* if you are a staff member, contact your Local Research Ethics Co-ordinator.

**APPROVAL PROCESS**

* Local Research Ethics Co-ordinator = LREC
* School level group (if your School uses a different review process, please follow your School guidance)
* University Research Ethics Sub-Committee = URESC

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| **Category** | **Student applicants** | **Staff applicants** |
| **Risk Category 1** | If your study has been provisionally classified as Risk Category 1, your Research Supervisor (or Director of Studies) can normally give approval for the project.  You must complete this form and submit it to your Research Supervisor for consideration.  A copy of the signed form if approved must be given or emailed to the LREC and, where relevant, the Research Module Leader, for information. | If your study has been classified as Risk Category 1, you do not need ethical approval for the project.  You must complete the remainder of this form so that your research project is registered with the University.  Please submit this form to your LREC. |
| **Risk Category 2** | If your study has been provisionally classified as Risk Category 2, your Supervisor (or Director of Studies) can recommend approval for your study by the LREC.  You must complete this application form and also the separate Stage 2 - Research Ethics Approval form.  Once you have completed the forms please submit both forms and supporting documentation to your Research Supervisor for consideration. Your Supervisor may disagree with your assessment and ask you to make revisions or reject your application. When the Research Supervisor is happy to recommend the application for approval, they will send the forms to the LREC.  The LREC will review your project and then decide to approve it, ask for revisions, reject it or pass it on for review by the School level group. | If your study has been provisionally classified as Risk Category 2, your project will be considered for ethical approval by the LREC.  You must complete this application form and also the separate Stage 2 - Research Ethics Approval form. Please submit both forms and supporting documentation to your LREC for consideration.  The LREC will review your project and then decide to approve it, ask for revisions or pass it on for review by the School level group. |
| **Risk Category 3** | **Postgraduate Research Students**  If your study has been provisionally classified as Risk Category 3, your Supervisor or Director of Studies can recommend approval for your study by the LREC.  You must complete this application form and also the separate Stage 2 - Research Ethics Approval form and submit both forms to your Director of Studies.  If your Director of Studies recommends approval of your project they will refer it to the LREC who will review your project and decide whether to grant ethical approval, request revisions, reject the application or refer it to the School level group for review.  **Undergraduate and Taught Postgraduate Students**  If your study has been provisionally classified as Risk Category 3, you should consult with your Research Supervisor immediately as it is unlikely you will be able to proceed and you should negotiate a project that is of lower risk. However, if you have already discussed the project with your Supervisor and they have agreed that a case for approval is warranted, proceed in line with the details above for Research Students. | If your study has been provisionally classified as Risk Category 3, your project will be considered for ethical approval by an appropriate LREC.  You must complete this application form and also the separate Stage 2 - Research Ethics Approval form and submit both forms with supporting documentation to your LREC.  The LREC will review your project and then decide to approve it, ask for revisions or pass it on for review by the School level group. |
| **Q23** | If question 23 has been answered ‘yes’, your application will be reviewed by the Chair of the University Research Ethics Sub-committee. The answer does not affect the Risk Category. | |